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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,416	02/22/2002	Oliver Yoa-Pu Hu	39297-174170	8467

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/079,416	Applicant(s) YOA-PU HU ET AL.	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16,33-44 and 46-51 is/are pending in the application.
 4a) Of the above claim(s) 10-16,33-43,46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 44 and 48-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/06 has been entered.

Status of Application

1. Claims 10-16, 33-44, and 46-51 are now pending and claims 44, 48-51 have been examined only to the extent that they read on use of the elected species in the claimed method.

All remaining(or portions thereof) claims not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejections are made.

Claim Objections

2. Claim 44 is objected to because of the following informalities: There is typographical error was found in claim 44, line 2 where the claimed term "cytochrome P450 1A" is inadvertently written as "cytochrome A 450 1A". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "said dermal CYP1A inhibitor " in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Eini et al(US5227163).

The claims are drawn to a composition comprising terpineol(as a dermal CYP1A inhibitor) and a carrier. Claim 51 requires terpineol(CYP1A inhibitor) present in the amount of about 10% by weight.

Eini et al(US'163, hereafter) teaches a composition comprising terpenoids(e.g. terpeneols(=terpineol)) in a concentration of between 0.01-50%,preferably 0.01-10%, by

weight and a pharmaceutically and/or cosmetically effective carrier, see abstract. It is noted that terpineol is a CYP1A inhibitor(self evidenced by instant claims 44 and 49) and thus claims are inherently met, see claims 1 and 7..

Claim 48 is properly included in this rejection because limitations recited in preamble(i.e. co-administration with a dermatological drug such as retinoic acid or retinoid is not consisted of main structure of the claimed invention which is a composition comprising terpineol and a carrier as required by claim 44, and thus, the structure of the of claimed invention is well taught by the teaching of the US'163 patent and thus, the claims are anticipated.

Applicant is reminded that the invention is drawn to a composition comprising a terpeniol and a carrier. If the composition taught by the reference of the record has same structured composition, the claims are met. The recitation(e.g. co-administration with other dermatological drug) in preamble is considered to be a description of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's arguments, the recitation(i.e. co-administration of a dermatological drug) is not included in the structure of the composition whereas the said

Art Unit: 1618

limitations should be included in method claims if there is any. And thus, said limitations have not been given patentable weight .

If applicant wishes to pursue independent invention(e.g. new use) from the invention previous elected and examined, applicant must file divisional or CIP to request for the examine such invention.

MPEP (2112) clearly states:

SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

"[T]he discovery of a previously unappreciated property of a prior art composition or a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas powder co. v. Ireco Inc.*, 190 F 3d 1342, 51 ISPQ2d 1943, 1947(Fed. Cir. 1999). Thus the claiming of a new use, new functioning or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F 2d 1252, 1254, 195 USPQ430, 433 (CCPA 1977). See also MPEP 2112.01 with regard to inherency and product-by-process claims and MPEP 2141.02 with regard to inherency and rejections under 35 USC 103.

Claim 49 requires a topical composition comprising terpeniol; a carrier; and additionally a dermatological drug.

US'163 teaches terpenol and a carrier containing lice repellent composition with additives such as other insect repellents, antimicrobials or antioxidants, see abstract.

Thus, the critical elements are well taught and the claim is met.

All the claims are properly maintained in 102 rejection and substantially same 102 rejection included in previous office action is repeated hereinabove.

Art Unit: 1618

3. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively as being obvious over Burger et al(US5759556).

Burger et al teaches a composition comprising terpineol in combination with retinols or retinyl esters for treating a variety of unwanted skin conditions, see abstract and columns 1-2. Since retinols or retinyl esters are specie of retinoids which is derivatives of retinoic acid(see the definition of retinoids in specification at page 5: line 5, "...retinoid is functional and structural derivatives of retinoic acid), the scope of the claims are encompassed by the teaching of the cited reference.

As described in patented claim 1, US'556 teaches all the critical elements such as terpineol, a carrier and a dermatological drug (i.e. retinoids).

Furthermore, the terpineol is present in an amount of about 0.01%to 10%.

Thus, all the critical elements required by the instant claims are well taught and the claims are properly anticipated by the cited reference.

In the case of that applicant argues deficiency of US556 patent due to lack of example, one would have been clearly envisaged the substitution with expectation of success, or at least the substitution is readily apparent because US'556 clearly suggest that the efficacy of substitution is well anticipated, and thus, one would have been motivated to employee terpineol instead of ionone or methylinone(exemplified species in examples 1-10), with reasonable expectation of success because it is always desired to extend the selection options for better availability for manufacture or improvement of industrial applicability.

Thus, the claimed invention is not patentably distinct over the prior art of the record.

4. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively as being obvious over Nonomura et al(US6020288).

US'288 teaches a composition for inducing cytochrome P450 monooxygenase, comprising a combination of terpenoids and retinoid, see abstract and claims, especially claim 32.

It is well known in the art that terpineol is terpenoids, a specie classified under terpenoids and thus, the claims are met by the cited reference. The examiner's allegation is commonly known and evidenced by prior art document, for example US'5227163(Eini, cited immediately above), see abstract.

At any event, the patent(US288), as taught in patented claim 32, utilizes a mixture of retinoid, terpenoid and alcohol. As known in the art, terpineol is terpenoid-alcohol(see US'163, abstract), and thus, a convenient form of terpenoids and alcohols mixture that is used to make up the patented composition. Therefore, one would have motivated to use terpeniol(terpenoid-alcohol) to increase the industrial applicability(by adding convenience and reducing the cost).

All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

5. Claims 44 and 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively as being obvious over Bortlik et al(US2002/0107292 A1).

6. US'292(Bortlik et al) teaches a composition for inducing cytochromoe P450 monooxygenase, comprising a combination of terpenoids and retinoid, see abstract and claim 7. For the very same reason set forth immediately above(Nonomura et al, US6020288), the claimed subject matter is not patentably distinct over the prior art of the record.

Conclusion

1. No claim is allowed.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 10/079,416

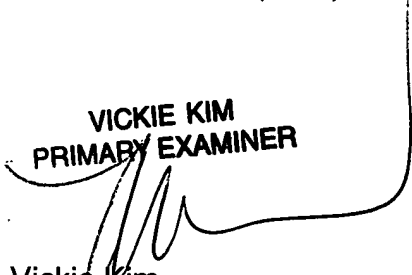
Page 9

Art Unit: 1618

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Vickie Kim', is written over the printed name and title. A long, thin horizontal line extends from the end of the signature to the right.

Vickie Kim
April 12, 2006
Art unit 1618